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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,567	12/17/2001	Robert S. Booker III	018803-002000US	2695

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,567

Applicant(s)

BOOKER ET AL.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,9-15,23-26 and 37 is/are rejected.
- 7) ☒ Claim(s) 2-8,16-22 and 27-36 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the blanks on page 3 must be appropriately filled, and the status of the applications referred to on page 1 of the specification should be updated if applicable.

Appropriate correction is required.

Claim Objections

2. Claims 1, 11 and 14 are objected to because of the following informalities: there is no positive recitation of the electrode surfaces on the planar region and the center region –merely an allusion to such surfaces. The examiner will assume it was the applicants' intent to include the electrode surfaces in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 9-15, 23, 24, 26 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (Pat. No. 5,365,926).

Regarding claim 1 and claims with similar limitations, Desai disclose a support (the region associated with the handle and shaft portion shown in Figs. 2 and 3), an electrode structure deployable from the support including a planar region (the region generally defining the plane comprising limbs 91 and electrode surfaces 80, 82, 84 and 86 when in the configuration shown in Fig. 4B) and a conformable, raised center region (that portion of the flexible insulation extending distally from slits 92 and raised from the plane containing electrodes 80, 82, 84 and 86 with electrode surface 90 thereon). The electrode surfaces on the planar region and the center region are electrically isolated

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from each other as necessary in order to provide the electrode combinations noted in column 5, lines 25-40.

Regarding claim 9, note separate leads 74 which connect individual electrode surfaces 80, 82, 84 and 86 to the power supply controller.

Regarding claim 10, lead 76 provides an electrically conductive path for center electrode surface 90, with conductive paths 74 connecting individual electrode surfaces as discussed above.

Regarding claim 12, the examiner considers the back plate electrode discussed in col. 6, lines 44-58 to constitute a paired counter electrode.

Concerning claim 13, the examiner considers the selector box discussed in col. 5, lines 41-50 to constitute a switch for switching between bipolar or unipolar electrode configurations (one can also consider the discussion found in lines 44-58 of col. 6 to relate to a switch for permitting bipolar operation as between the center electrode and the peripheral electrodes, and unipolar operation as between the center electrode and backing plate). The particular reason for switching is considered to be a recitation of an intended use for the switch. In any event, Desai discloses that sensing may be performed in a bipolar configuration and that high energy of 100-300 Joules (i.e., sufficient to defibrillate) may be applied in a unipolar fashion with the backing plate.

Addressing claim 14, the examiner considers the distal tip of the flexible tube 20 to be a blunt tip, with center electrode 90 attached thereto.

Regarding claim 15, the examiner considers the electrically conductive base to comprise that portion of the stem within tube 20' (Fig. 5) and connected to conductor 24'. The examiner considers electrode 90 shown in Fig. 4C to comprise a conductive dome.

Concerning method claim 23, the interpretation of the Desai reference discussed in the rejection of claim 1 applies here as well, with the percutaneous insertion discussed in col. 4, lines 37-42.

Regarding kit claim 37, since Desai is considered by the examiner to disclose the method of claim 23, merely writing known instructions for a known product and combining the two in a kit form would have been considered obvious by those of

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ordinary skill in the medical art. Clearly proper use of an invasive medical device would have been considered very important to the patient's health, thus requiring a set of instructions for the surgeon to follow to ensure correct operation. In any event, even if the method were to be considered a new use of an old product, the applicants are not entitled to patent a known product by simply attaching a set of instructions to that product (see *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983)).

5. Claims 1, 9-15, 23-26 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (Pat. No. 5,433,198).

The application of Desai '198 to claims 1, 9-15, 23, 24, 26 and 37 is substantially identical to that set forth above in the rejection under Desai '926.

Specifically regarding claim 25, note col. 6, lines 52-66 wherein pacing is enacted by connection of the multi-electrode catheter 70 to the pacing unit 40.

Allowable Subject Matter

6. Claims 2-8, 16-22 and 27-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Concerning claim 2, the prior art of record does not appear to disclose the recited arrangement between the base, dome, and spacer in an electrode of the type disclosed in claim 1.

Regarding claim 7, there is no teaching in the prior art of record for modifying the invention of Desai to include the recited fixed non-conductive rod. The cable element in Desai is conductive in order to allow the center electrode to apply energy to the heart. It is not clear that it would have been obvious to add a non-conductive rod in addition to the conductive cable since the catheter of Desai is intended to be flexible and small in diameter to allow for ease of entry into the heart. The purpose of the present invention, however, is to allow for cardiac massage and thus a more rigid design is necessary to allow for the required compression forces to be translated to the distal end.

Concerning claims 16 and 27, the prior art does not disclose the use of an electrically conductive compliant web and a soft matrix or mesh conductive dome in an electrode of the type set forth in the parent claims.

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Regarding claim 31, there is no teaching in the prior art of record for modifying the invention of Desai to include the step of compressing the heart by pressing the electrode structure against the heart. Webster's defines the word "compression" to connote the act of making an object more compact by pressure or the like.

Regarding method claim 35, there is no impetus to utilize the electrode structure of Desai to apply defibrillation energy between one of the catheter electrodes and a counter electrode on the patient's back to defibrillate the heart. Although a counter electrode can be placed on the patient's back in the invention described by Desai, the energy applied ablates the cardiac tissue due to the relatively small-sized catheter electrodes and concomitant high current densities.

Conclusion

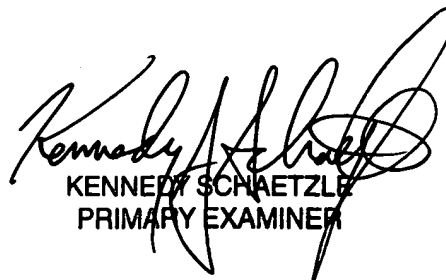
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 4, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER